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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/017,568   | 12/14/2001  | Michael B. Zemel     | UTR-104C1           | 9941             |
| 26694  | 7590        | 03/13/2007           | EXAMINER            |                  |
| VENABLE LLP<br>P.O. BOX 34385<br>WASHINGTON, DC 20043-9998 |             |                      | WEBMAN, EDWARD J    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1616                |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE                     |             | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS   |             | 03/13/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/017,568             | ZEMEL ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Edward J. Webman       | 1616                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 December 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-27,29 and 35-68 is/are pending in the application.
- 4a) Of the above claim(s) 22,25-27,29,42-49,51-54,59,60,62 and 64-68 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21,23,24,35-41,50, 55-58,61, 63 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 23-24, 35-41, 50, 53, 55-58, 61, 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zemel et al (FASEB J., 6/2000, v. 14, p. 1132) in view of Norman et al (JBC 11/25/98, v. 508(27), p. 20022).

Zemel et al teach that 1 alpha, 25-dihydroxyvitamin D3 induces an increase in calcium ion concentration in adipocytes and a concomitant inhibition of lipolysis (abstract).

Norman et al teach that 1 beta, 25-dihydroxyvitamin D3 is an antagonist of the 1 alpha compound, particularly calcium ion uptake (title, 2<sup>nd</sup> para. in abstract). A receptor biologically different from the nuclear receptor is implicated. (page 20022, right column second paragraph).

It would have been obvious to one of ordinary skill to use the 1 beta compound to control weight in view of the fact that Zemel et al teach that the 1, alpha compound inhibits lipolysis and that the beta compound blocks the action of the alpha compound. One of ordinary skill would recognize that blocking 1, alpha compound will promote lipolysis and, therefore, weight loss. As to the claimed reduction in risk of coronary artery disease, one of ordinary skill, in fact, even a layman, will recognize that weight loss will reduce the risk of said disease. As to the claimed liquid vehicle, an alcoholic would be an obvious expedient in view of the multiple hydroxyl groups carried by the

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compound. As to the claimed grades of obesity, one of ordinary skill would use the obvious treatment for all grades, given that the grades merely indicate degrees of obesity.

Applicants argue that the filing date of the parent patent Us 6,384,087 is 9/1/00, therefore, the critical date is 9/1/99. However, the face of the patent does not indicate any earlier priority date, such as for a provisional application, filed on such a date. Thus, the critical date before which references must have been published to be used as prior art is 9/1/00. The primary reference was published before this date, therefore, the rejection stands.

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



EDWARD J. WEBMAN  
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